510K Summary:

JUL - 7 2011

SUBMITTER:	Neomedic International, S.L. C/ Maestrat 41-43 1º 08225 Terrassa (Barcelona) Spain
DATE PREPARED:	September 12th, 2010
DEVICE NAME:	Surelift Prolapse System
CLASSIFICATION NAMES:	Mesh, Surgical, Polymeric
PREDICATE DEVICES:	AMS ELEVATE WITH INTERPRO LITE PROLAPSE REPAIR SYSTEM, AMS ELEVATE WITH INTEXEN LP PROLAPSE REPAIR SYSTEM GYNECARE PROLIFT +M* PELVIC FLOOR REPAIR SYSTEMS

Device Description:

The Surelift Prolapse System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and posterior vaginal wall prolapse. The kit includes instrumentation for transvaginal placement.

The kit is composed by a monofilament polypropylene mesh, two anchors with sutures to fix the mesh at the sacrospinose ligament, two anchoring handles to place the anchors and four passers to place the mesh through the obturator foramens.

The mesh has six fixation points (two posterior fixation points and four arms):

- Two posterior fixation points that are fixed to the sacrospinose ligaments.
- Two middle arms that are passed through the arcus tendineus.
- Two anterior arms that are passed through the anterior part of the obturator foramen.

When placing the mesh, these six fixation points can be adjusted by the surgeon to leave the mesh flat at the proper tension avoiding wrinkles.

Description of material components and physical properties:

Component	Material
Monofilament polypropylene mesh	Polypropylene monofilament
Monofilament polypropylene sutures	Polypropylene monofilament
Anchors	PEEK
Anchoring Handle	Stainless steel AISI 303 POM
Passers	Stainless steel AISI 303 POM

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Component	Properties
Monofilament polypropylene mesh	Knitted mesh Monofilament diameter = 0,12 mm Tensile break strength = 81,87 Newton Pore size = 1,12 mm Thickness = 0,41 mm Density = 41,60 g/m^2 Porosity = 54,63 %
Monofilament polypropylene sutures	USP 0
Anchors	Diameter: 3 mm Length: 7 mm
Anchoring Handles	Anchoring Handle tube diameter = 6 mm Anchoring Handle tube length = 204 mm
Passers	Passers diameter = 4 mm

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Predicate Devices:

The following two devices have been previously cleared by the FDA in the following 510(K)

Device	510 (K) document number	Date Cleared	Indications
AMS ELEVATE WITH INTERPRO LITE PROLAPSE REPAIR SYSTEM, AMS ELEVATE WITH INTEXEN LP PROLAPSE REPAIR SYSTEM	K080185	April 10 2008	Pelvic Floor Repair System
GYNECARE PROLIFT +M* PELVIC FLOOR REPAIR SYSTEMS	K071512	May 15 2008	Pelvic Floor Repair System

Intended Use:

The Surelift Prolapse System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and posterior vaginal wall prolapse. The kit includes instrumentation for transvaginal placement.

Technological Characteristics comparison:

The Surelift prolapse system and the two predicate devices are substantially equivalent:

The two predicate devices are intended for pelvic floor prolapse repair.
The two predicate devices use monofilament polypropylene mesh and have multi-arm design for mesh adjustment and fixation.
The two predicate devices include accessories to aid in mesh placement.
One of the predicate devices (AMS) uses anchors to fixate the mesh to the sacrospinose ligament.
The two predicate devices are sterilized by ETO.

There are differences compared to the predicate devices:

1.- The design of the arms is different: The Surelift has six fixation points (two posterior fixation points and four arms), the AMS Elevate has four fixation points (two posterior fixation points and two arms) and the Prolift has four fixation points (four arms).
Surelift fixation points: two posterior fixation points (sacrospinose ligament), two medium arms (Arcus tendineus) and two anterior arms (anterior obturator foramen).
AMS Elevate fixation points: two posterior fixation points (Sacrospinose ligament) and two anterior arms (anterior obturator foramen).
Prolift fixation points: two medium arms (Arcus tendineus) and two anterior arms (anterior obturator foramen).

2.- The anchor material of the AMS Elevate is polypropylene, and the anchor material of the Surelift is PEEK.

The differences between the three devices do not raise new questions on the safety and effectiveness. We consider the proposed device is substantially equivalent to the predicate devices.

Performance tests:

Performance test	Test description
Sterilization	Bioburden Ethylene oxide residuals Ethylene chlorohydrins residuals Sterility assurance level (SAL) determination
Packaging	Expiration dating test
Biocompatibility	Cytotoxicity Implantation Sensitization with polar and non-polar extract Genotoxicity Acute systemic toxicity Irritation Haemolysis Extractable metallic ions Pyrogen test
Mechanical tests	Suture pullout strength Tensile break strength at break Tear resistance Burst strength Stiffness Pore size Thickness Density Porosity Prolapse anchor-mesh strength Prolapse arm tensile strength

Results of verification testing indicate that the product meets the established performance requirements and standards.

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the proposed device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neomedic International S.L.
c/o Jeffrey R. Shideman, Ph.D.
President
International Medical Products Corporation
7307 Glouchester Drive
EDINA MN 55435

SEP 28 2012

Re: K102815
Trade Name: Surelift Prolapse System
Regulation Number: 21 CFR §878.3300
Regulation Name: Surgical Mesh
Regulation Class: II
Product Code: OTP
Dated: June 28, 2011
Received: June 30, 2011

Dear Dr. Shideman:

This letter corrects our substantially equivalent letter of July 7, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

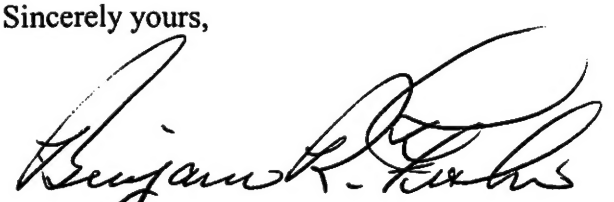
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K102815**

Device Name: SURELIFT PROLAPSE SYSTEM

Indications for Use:

The SURELIFT PROLAPSE SYSTEM is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and posterior vaginal wall prolapse. The kit includes instrumentation for transvaginal placement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102815